

K963539

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510(K) NOTIFICATION

**Sigma Diagnostics
545 South Ewing Avenue
St. Louis, MO 63103**

**CX³ Wash Concentrate
Procedure Number W0129
August 31, 1996**

SUMMARY OF SAFETY AND EFFECTIVENESS

The Wash Concentrate is diluted to prepare Wash Solution, a dilute solution of wetting agents and preservatives. It is formulated to serve as a reagent diluent and a wash solution for the SYNCHRON CX³ and all of its chemistries. The diluent allows the use of concentrated reagents that exhibit improved open stability over more dilute reagents.

The safety and effectiveness of Sigma Diagnostics Wash Concentrate, Procedure Number W0129, are demonstrated by its substantial equivalency to Beckman Wash Concentrate Solution Kit, Part No. 443335.